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EXAMINER
YOUNG, JOSEPHINE

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 06/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No. 10/021,502	Applicant(s) GLOMBIK ET AL.	
	Examiner Josephine Young	Art Unit 1623	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Peri d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-17* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, 4 and 5-8 drawn to compounds of the Formula I with only one (C_0-C_{30})alkylene-(LAG) radical, LAG being a sugar residue, disugar residue, trisugar residue, tetrasugar residue, a sugar acid or an amino sugar, and pharmaceutical compositions comprising such compounds, classified in class 536, subclass 17.4.

II. Claims 1-3 and 5-8, drawn to compounds of the Formula I with only one (C_0-C_{30})alkylene-(LAG) radical, LAG being an amino acid residue or an oligopeptide residue, and pharmaceutical compositions comprising such compounds, classified in class 530, subclass 300^+.

III. Claims 1-3 and 5-8, drawn to compounds of the Formula I with only one (C_0-C_{30})alkylene-(LAG) radical, LAG being a trialkylammoniumalkyl radical, and pharmaceutical compositions comprising such compounds, classified in class 540, subclass 200.

IV. Claims 1-3 and 5-8, drawn to compounds of the Formula I with only one (C_0-C_{30})alkylene-(LAG) radical, LAG being –O-(SO_2)-OH, and pharmaceutical compositions comprising such compounds, classified in class 540, subclass 200.

V. Claims 1-3 and 5-8, drawn to compounds of the Formula I with more than one (C_0-C_{30})alkylene-(LAG) radical, and pharmaceutical compositions comprising such compounds, classified in class 540, subclass 200.

VI. Claims 9-12, drawn to methods for the treatment of impaired lipid metabolism, including hyperlipidemia, using compounds of the Formula I with only one (C_0-C_{30})alkylene-(LAG) radical, LAG being a sugar residue, disugar residue, trisugar residue, tetrasugar residue, a sugar acid or an amino sugar, classified in class 514, subclass 25.

VII. Claims 9-12, drawn to methods for the treatment of impaired lipid metabolism, including hyperlipidemia, using compounds of the Formula I with only one (C_0-C_{30})alkylene-(LAG) radical, LAG being an amino acid residue or an oligopeptide residue, classified in class 514, subclass 2^+.

VIII. Claims 9-12, drawn to methods for the treatment of impaired lipid metabolism, including hyperlipidemia, using compounds of the Formula I with only one (C_0-C_{30})alkylene-(LAG) radical, LAG being a trialkylammoniumalkyl radical, classified in class 514, subclass 210.02.

IX. Claims 9-12, drawn to methods for the treatment of impaired lipid metabolism, including hyperlipidemia, using compounds of the Formula I with only one (C_0-C_{30})alkylene-(LAG) radical, LAG being –O-(SO_2)-OH, classified in class 514, subclass 210.02.

X. Claims 9-12, drawn to methods for the treatment of impaired lipid metabolism, including hyperlipidemia, using compounds of the Formula I with more than one (C_0-C_{30})alkylene-(LAG) radical, classified in class 514, subclass 210.02.

XI. Claim 13, drawn to methods for controlling serum cholesterol concentration, using compounds of the Formula I with only one (C_0-C_{30})alkylene-(LAG) radical,

LAG being a sugar residue, disugar residue, trisugar residue, tetrasugar residue, a sugar acid or an amino sugar, classified in class 514, subclass 25.

XII. Claim 13, drawn to methods for controlling serum cholesterol concentration, using compounds of the Formula I with only one (C_0-C_{30})alkylene-(LAG) radical, LAG being an amino acid residue or an oligopeptide residue, classified in class 514, subclass 2^+.

XIII. Claim 13, drawn to methods for controlling serum cholesterol concentration, using compounds of the Formula I with only one (C_0-C_{30})alkylene-(LAG) radical, LAG being a trialkylammoniumalkyl radical, classified in class 514, subclass 210.02.

XIV. Claim 13, drawn to methods for controlling serum cholesterol concentration, using compounds of the Formula I with only one (C_0-C_{30})alkylene-(LAG) radical, LAG being –O-(SO_2)-OH, classified in class 514, subclass 210.02.

XV. Claim 13, drawn to methods for controlling serum cholesterol concentration, using compounds of the Formula I with more than one (C_0-C_{30})alkylene-(LAG) radical, classified in class 514, subclass 210.02.

XVI. Claims 14-15, drawn to methods for treating insulin resistance, using compounds of the Formula I with only one (C_0-C_{30})alkylene-(LAG) radical, LAG being a sugar residue, disugar residue, trisugar residue, tetrasugar residue, a sugar acid or an amino sugar, classified in class 514, subclass 25.

XVII. Claims 14-15, drawn to methods for treating insulin resistance, using compounds of the Formula I with only one (C_0-C_{30})alkylene-(LAG) radical, LAG being an amino acid residue or an oligopeptide residue, classified in class 514, subclass 2^+.

XVIII. Claims 14-15, drawn to methods for treating insulin resistance, using compounds of the Formula I with only one (C_0-C_{30})alkylene-(LAG) radical, LAG being a trialkylammoniumalkyl radical, classified in class 514, subclass 210.02.

XIX. Claims 14-15, drawn to methods for treating insulin resistance, using compounds of the Formula I with only one (C_0-C_{30})alkylene-(LAG) radical, LAG being –O-(SO_2)-OH, classified in class 514, subclass 210.02.

XX. Claims 14-15, drawn to methods for treating insulin resistance, using compounds of the Formula I with more than one (C_0-C_{30})alkylene-(LAG) radical, classified in class 514, subclass 210.02.

XXI. Claims 16-17, drawn to methods for the treatment of an arteriosclerotic manifestation, using compounds of the Formula I with only one (C_0-C_{30})alkylene-(LAG) radical, LAG being a sugar residue, disugar residue, trisugar residue, tetrasugar residue, a sugar acid or an amino sugar, classified in class 514, subclass 25.

XXII. Claims 16-17, drawn to methods for the treatment of an arteriosclerotic manifestation, using compounds of the Formula I with only one (C_0-C_{30})alkylene-(LAG) radical, LAG being an amino acid residue or an oligopeptide residue, classified in class 514, subclass 2^+.

XXIII. Claims 16-17, drawn to methods for the treatment of an arteriosclerotic manifestation, using compounds of the Formula I with only one (C_0-C_{30})alkylene-(LAG) radical, LAG being a trialkylammoniumalkyl radical, classified in class 514, subclass 210.02.

XXIV. Claims 16-17, drawn to methods for the treatment of an arteriosclerotic manifestation, using compounds of the Formula I with only one (C_0-C_{30})alkylene-(LAG) radical, LAG being –O-(SO_2)-OH, classified in class 514, subclass 210.02.

XXV. Claims 16-17, drawn to methods for the treatment of an arteriosclerotic manifestation, using compounds of the Formula I with more than one (C_0-C_{30})alkylene-(LAG) radical, classified in class 514, subclass 210.02.

Claims 1-3 and 5-8 link Groups I-V and will be examined together with the Group that is elected as it pertains to the elected invention. Claims 9-12 link Groups VI-X and will be examined together with the Group that is elected as it pertains to the elected invention. Claim 13 links Groups XI-XV and will be examined with the Group that is elected as it pertains to the elected invention. Claims 14-15 link Groups XVI-XX and will be examined together with the Group that is elected as it pertains to the elected invention. Claims 16-17 link Groups XXI-XXV and will be examined together with the Group that is elected as it pertains to the elected invention.

The inventions are distinct, each from the other because of the following reasons:

Groups I-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to patentably distinct compounds with different functions. Group I is directed to diphenylazetidinones that are functionalized with a sugar-based moiety. Group II is directed to diphenylazetidinones that are functionalized with an amino acid-based moiety. Group III is directed to diphenylazetidinones that are functionalized with a trialkylammoniumalkyl radical. Group IV is directed to diphenylazetidinones that are functionalized with a sulphate. Group V is directed to diphenylazetidinones that are functionalized with more than one chemically distinct moiety. Therefore, the compounds of one do not render obvious the compounds of another.

Groups I-V are related to Groups VI-X as product and process of use. Similarly, Groups I-V are related to Groups XI-XV as product and process of use; Groups I-V are related to Groups XVI-XX as product and process of use; and Groups I-V are related to Groups XXI-XXV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in materially different processes, such as for the treatment of impaired lipid metabolism, as per Groups VI-X; for controlling serum cholesterol concentration, as per Groups XI-XV; for treating insulin resistance, as per Groups XVI-XX; or for the treatment of an arteriosclerotic manifestation, as per Groups XXI-XXV.

Groups VI-X, Groups XI-XV, Groups XVI-XX and Groups XXI-XXV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to patentably distinct methods with different effects. The effect of Groups VI-X is the treatment of impaired lipid metabolism. The effect of Groups XI-XV is controlled serum cholesterol concentration. The effect of Groups XVI-XX is the treatment of insulin resistance. The effect of Groups XXI-XXV is the treatment of an arteriosclerotic manifestation. Therefore, the methods of one do not render obvious the methods of another.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, restriction for examination purposes as indicated is proper. A reference for one group could not reasonably be expected to be a reference for another. Further, searching all of the inventions constitutes a burdensome search, as a thorough search comprises a search of foreign patents and non-patent literature, as well as the appropriate U.S. patent classifications. To search the twenty-five independent and distinct inventions, set forth supra, would indeed impose an undue burden upon the examiner in charge of this application.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even if the requirement is traversed (37 CFR 1.143).

Election of Species

If one of Groups I-IV is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, the claims are generic to a plurality of disclosed patentably distinct species wherein:

each species is a compound with a distinct location for the (C_0-C_{30})alkylene-(LAG) radical, i.e.

(A) R1 or R2 is the (C_0-C_{30})alkylene-(LAG) radical;

(B) R3 or R4 is the (C_0-C_{30})alkylene-(LAG) radical; or

(C) R5 or R6 is the (C_0-C_{30})alkylene-(LAG) radical;

AND

the (C_0-C_{30})alkylene is a patentably distinct linker, for example the linker of Example I, Example IX, Example XXIII, etc.

Similarly, if one of Groups VI-IX, XI-XIV, XVI-XIX or XXI-XXIV is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species wherein each species is a method of using a compound with a distinct location for the (C_0-C_{30})alkylene-(LAG) radical AND a patentably distinct (C_0-C_{30})alkylene derived linker, as set forth supra, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

If Group V is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, the claims are generic to a plurality of disclosed patentably distinct species wherein:

each species is a compound with a distinct location for the (C_0-C_{30})alkylene-(LAG) radicals (A-C);

AND

each LAG moiety is patentably distinct, for example a sugar-based moiety, an amino acid based moiety, a trialkylammoniumalkyl radical, or a sulphate;

AND

the (C_0-C_{30})alkylene is a patentably distinct linker, for example the linker of Example I, Example IX, Example XXIII, etc.

Similarly, if one of Groups X, XV, XX or XXV is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species wherein each species is a method of using a compound with a distinct location for the (C_0-C_{30})alkylene-(LAG) radical AND each LAG moiety is patentably distinct AND a patentably distinct (C_0-C_{30})alkylene derived linker, as set forth supra, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Josephine Young whose telephone number is (703) 605-1201. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at (703) 308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

JY
May 30, 2003

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600